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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,919	11/21/2001	Roberto Macina	DEX-0289	2841

7590 01/22/2004

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EXAMINER
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MARTINELL, JAMES

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/989,919

Applicant(s)

MACINA ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

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The amendment filed November 5, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "a-mating system" (page 49, line 3).

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The attempt to incorporate subject matter into this application by reference to material accessible (*i.e.* "published") only via hyperlinks and/or other forms of browser-executable codes is improper because this material is not an allowed U.S. Patent application or issued U.S. Patent (see MPEP 608.01(p)). The material referred to is admitted by applicants to be essential (response filed November 5, 2003, paragraph bridging pages 7-8).

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants acknowledge that the material referred to via hyperlinks and/or other forms of browser-executable codes is necessary for the application to

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comply with 35 U.S.C. §112, first paragraph. Since the incorporation of said material by reference is improper (see the objection hereinabove), the application does not enable one of skill in the art to practice the claimed invention without performing undue experimentation.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9, 14, and 15 are rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility. This rejection is repeated for reasons already of record (e.g., Office action mailed August 4, 2003, page 3). Applicants' arguments (response filed November 5, 2003, page 9) are not convincing because applicants do not point with specificity where the instant application shows a connection between SEQ ID NO: 15 and colon cancer or whether SEQ ID NO: 15 is specific for colon cancer. Applicants' argument in connection with Diachenko et al (Proc. Natl. Acad. Sci. USA 93: 6025 (1996)) is not convincing because a copy of the reference is not in the record. In addition, that a method is designed to achieve a purpose does not demonstrate that the method has actually achieved that purpose for a specific nucleic acid sequence. Finally, in order to be shown to be colon specific, the sequence needs to be compared to all other tissues and organs of the body. No such evidence has been indicated in applicants' arguments. For example, the meaning of "DEX0289\_15 flexDEX0133\_9

DEX0289\_84" (instant application, page 117, line 3) is not understood to show SEQ ID NO: 15 to be either specifically expressed in colon tissues or to be in any way connected to colon cancer or to be useful in the diagnosis or treatment of colon cancer or any other cancer.

Claims 1-9, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for reasons already of record (e.g., Office action mailed August 4, 2003, page 3). The discussion in the rejection under 35 USC § 101 hereinabove is incorporated here.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite.

- (a) The recitation of "colon specific nucleic acid" (claim 6) is vague and indefinite because the term is not clearly defined. This rejection is repeated for reasons already of record (e.g., Office action mailed August 4, 2003, page 4). Applicants' argument (response filed November 5, 2003, page 11) is not convincing. The term is used on pages 6 and 31 of the instant application, but it is not defined in either of those places.

Claims 1-5, 7-9, and 15 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Rosen et al (WO 01/55323 (August 2, 2001)). This rejection is repeated for reasons already of record (e.g., Office action mailed August 4, 2003, page 5). Applicants assert (response filed November 5, 2003, page 14) that the amendment of claim 1(d) to recite "a nucleic acid molecule having at least 95% sequence identity to the amino acid molecule of (a) or (b)" renders the claims free of the prior art. This argument is not convincing because part (c) of claim 1 recites "a nucleic acid molecule that hybridizes under stringent conditions to the nucleic acid molecule of (a) or (b)". Since the DNA of Rosen et al is 92.0% similar to SEQ ID NO: 15, it would hybridize to SEQ ID NO: 15 under stringent conditions and therefore is embraced by Claim 1(c).

Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Waterston et al (GenBank® Accession No. AC13480 (November 12, 1999)). This rejection is repeated for reasons already of record (e.g., Office action mailed August 4, 2003, page 5). Applicants assert (response filed November 5, 2003, page 14) that the amendment of claim 1(d) to recite "a nucleic acid molecule having at least 95% sequence identity to the amino acid molecule of (a) or (b)" renders the claims free of the prior art. This argument is not convincing because part (c) of claim 1 recites "a nucleic acid molecule that hybridizes under stringent conditions to the nucleic acid molecule of (a) or (b)". Since the DNA of Waterston et al is 93.7% similar to SEQ ID NO: 15, it would hybridize to SEQ ID NO: 15 under stringent conditions and therefore is embraced by Claim 1(c).

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

**PLEASE NOTE THE NEW FAX NUMBER**

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
**James Martinell, Ph.D.**  
**Primary Examiner**  
**Art Unit 1631**